

## **REMARKS**

### **RESTRICTION REQUIREMENT:**

#### **Basis For Traverse**

According to MPEP § 803, a restriction requirement between patentably distinct inventions is only proper when:

- 1) The inventions are independent or distinct; and
- 2) There is a serious burden on the Examiner if restriction is not required.

A rebuttable prima facie showing of a serious burden can be made if the Examiner shows by appropriate explanation either separate classification, status in the art, or a different field of search as defined in MPEP § 808.02.

Applicants note that to establish a rebuttable presumption of a serious burden, the Examiner must show by appropriate explanation either separate classification, status in the art, or a different field of search as defined in MPEP § 808.02. While Applicants are aware that the Examiner need not cite patents to show a different field of search, according to MPEP § 808.02, the Examiner must provide, at a minimum, an appropriate explanation to establish a rebuttable prima facie showing of a serious burden.

Examiner contends that the product in the instant case can be used in a materially different process of using that product, such as promoting wound or bone fracture healing. Applicants submit that the process of treating or preventing a disease, as amended herein, covers the above examples provided by the Examiner, per the dictionary definitions of disease (The dictionary listings are provided on page 16 of this paper). Accordingly, Applicants submit that it would not be necessary to conduct different searches for the product claimed (as amended herein) and the process of using said product. Applicants also assert that an art search for a device, “having a ring-like structure and for implanting in the vasculature or cardiovascular, for treating a disease, that comprises a biodegradable matrix material capable of dissolving upon contact with blood and at least one drug capable of being released into the blood stream as the biodegradable matrix material dissolves, said device being capable of degrading gradually and completely as the biodegradable matrix material dissolves” would be expected to yield the art that is pertinent to the patentability of a method of treatment or prevention of a disease that comprises “the deployment of the claimed device (as amended herein) into a vessel of a patient’s body, and the release of a drug into the patient’s blood stream over a period of time as the

biodegradable matrix material dissolves upon contact with the blood and the device degrades”. In that, Applicants assert that the process of use claims of Group II are limited for use with the amended device claims of Group I, hence the amended process of use claims of Group II are not independent or distinct from Group I claims. As a result of the foregoing, Applicants respectfully submit that the restriction of Applicants’ claims is improper and should be withdrawn.

However, in order to be fully responsive to the restriction requirement in the present application, Applicants provisionally elect, with traverse, to prosecute the claims identified as Group I (device claims 1-22; being the now amended claims 1, 3-6, 8-22). Applicants make this election with the understanding that if the device claims of this application become patentable, Applicants will request the rejoinder of the process of use claims in this application.

#### **PRELIMINARY AMENDMENT:**

The Specification has been amended at page 5 at paragraphs beginning on line lines 11 and 17, page 6 at paragraph beginning on line 18, at page 25 at paragraph beginning on line 12, and at page 25 in Table I, to specify the generic names of the branded drugs Taxol®, Celebrex® and Aldactone®, and the brand names of the generic drugs flecainide, abciximab, ibutilide, and losartan. No new matter has been added.

Claims 1, 3-6, 8-23, 25 and 27-30 have been amended to more clearly claim the Applicants’ invention. Claims 4, 9, 27 and 29 have been amended to correct typographical and/or grammatical errors. Claim 1 has also been amended to incorporate a limitation of originally filed claim 2. Claims 9 and 27 have been amended to specify the generic names of branded drugs Aldactone®, Celebrex® and Taxol®. Claim 9 has also been amended to include a resin, fibrate, niacin, and statin as a drug choice. Claim 23 has also been amended to depend from claim 1. Claims 2, 7, 24 and 26 have been cancelled, without prejudice. Support for these amendments may be found throughout Applicants’ Specification and Drawings, for example at page 12, line 17; page 14, lines 16 and 20; page 15, line 6; page 16, line 7; page 22, line 5; page 25, line 14, and originally filed claims 2 and 27. No new matter has been added.

## **CONCLUSION**

In view of the election and remarks presented herein, Applicants submit that the Applicants are fully responsive to the restriction requirement.

This response to the restriction requirement has been timely filed. Accordingly, no additional fee is required.

It is respectfully requested that this first preliminary amendment presented herein be entered before the examination of this application. No fees are believed to be due by the present amendments.

Should the Examiner have any questions or requires any additional information from Applicant's attorney, the Examiner is invited to contact the undersigned.

Respectfully submitted,

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**Definitions of “disease”:**

(obtained from: <http://dictionary.reference.com/browse/disease>)

**Merriam-Webster's Medical Dictionary:**

An impairment of the normal state of the living animal or plant body or one of its parts that interrupts or modifies the performance of the vital functions and is a response to environmental factors (as malnutrition, industrial hazards, or climate), to specific infective agents (as worms, bacteria, or viruses), to inherent defects of the organism (as genetic anomalies), or to combinations of these factors.

**American Heritage Dictionary:**

A pathological condition of a part, organ, or system of an organism resulting from various causes, such as infection, genetic defect, or environmental stress, and characterized by an identifiable group of signs or symptoms.

**Dictionary.com Unabridged (v 1.1):**

A disordered or incorrectly functioning organ, part, structure, or system of the body resulting from the effect of genetic or developmental errors, infection, poisons, nutritional deficiency or imbalance, toxicity, or unfavorable environmental factors; illness; sickness; ailment.

**Wikipedia, the free encyclopedia:**

A disease is an abnormal condition of an organism that impairs bodily functions. In human beings, "disease" is often used more broadly to refer to any condition that causes discomfort, dysfunction, distress, social problems, and/or death to the person afflicted, or similar problems for those in contact with the person. In this broader sense, it sometimes includes injuries, disabilities, disorders, syndromes, infections, isolated symptoms, deviant behaviors, and atypical variations of structure and function, while in other contexts and for other purposes these may be considered distinguishable categories.